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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,094	06/25/2003	Don J. Diamond	1954-410	7356
6449	7590	11/29/2007	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			HUMPHREY, LOUISE WANG ZHIYING	
1425 K STREET, N.W.			ART UNIT	PAPER NUMBER
SUITE 800			1648	
WASHINGTON, DC 20005				
NOTIFICATION DATE		DELIVERY MODE		
11/29/2007		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/603,094	DIAMOND, DON J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 September 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4 and 12-14 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 2 and 5-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

This Office Action is in response to the amendment filed 13 September 2007.

Claims 1-14 are pending. Claims 3, 4 ad 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 1, 2 and 5-11 are currently examined.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1, 2, 5, 6 and 9-11 under 35 U.S.C. §103(a) as being unpatentable over the Australian patent No. PR5931 (26 June 2001) in view of Livingston *et al.* (1999, No.YY in IDS filed on 08 March 2004) and Krieg *et al.* (WO122972, 30 Apr 2001) is **withdrawn** in view of the newly discovered prior art. See the following new rejections.

### ***NEW REJECTION - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Zaia *et al.* (2000, No. QQQQ in IDS filed on 08 March 2004).

The instant claims are drawn to a cytomegalovirus (CMV) vaccine, which comprises a fusion peptide composed of a T helper epitope fused to a CMV CTL epitope peptide. Claims 2 and 11 further limit the T helper epitope to a PADRE. Claims 5 and 6 further limit the CMV CTL epitope to pp65 peptides.

Zaia *et al.* teach a fusion peptide comprising CMV CTL epitope pp65 (495-503) fused to the T helper epitope PADRE. See page 351, 2<sup>nd</sup> column, last paragraph, and page 352, Table 2.

Therefore, claims 1, 2, 5, 6 and 9-11 are anticipated by Zaia *et al.*

### ***NEW REJECTION - 35 USC § 103***

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Zaia *et al.* (2000, No. QQQQ in IDS filed on 08 March 2004) in view of Krieg *et al.* (WO122972, 30 Apr 2001).

The instant claims are drawn to a cytomegalovirus vaccine which comprises a fusion peptide composed of a T helper epitope fused to a CMV CTL epitope peptide. Claims 7 and 8 further limit the vaccine to comprise a DNA adjuvant

Zaia *et al.* teach a fusion peptide comprising CMV CTL epitope pp65 (495-503) fused to the T helper epitope PADRE. See page 351, 2<sup>nd</sup> column, last paragraph, and page 352, Table 2. Zaia *et al.* do not teach a DNA adjuvant.

However, Krieg *et al.* describe immunostimulatory nucleic acids. Specifically, Krieg *et al.* disclose a DNA that matches the sequence of the instantly claimed SEQ ID NO:10. See page 57, SEQID NO:959, in Table A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the CMV vaccine of Zaia *et al.* by adding a DNA adjuvant as taught by Krieg *et al.* The skilled artisan would have been motivated to do so to enhance the amount of immune response elicited by the HCMV pp65 CTL epitope. There would have been a reasonable expectation of success, given the disclosure that these DNA adjuvants preferentially activate non-rodent immune cells, as taught by Krieg *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

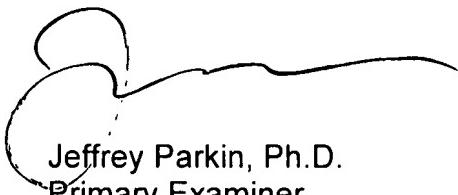
### ***Correspondence***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
20 November 2007



Louise Humphrey, Ph.D.  
Assistant Examiner